

(2) As substitutes for the corresponding naturally derived fatty alcohols used as intermediates in the synthesis of food additives and other substances permitted in food.

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 11837, Mar. 19, 1982; 49 FR 10105, Mar. 19, 1984; 54 FR 24897, June 12, 1989]

**§ 172.866 Synthetic glycerin produced by the hydrogenolysis of carbohydrates.**

Synthetic glycerin produced by the hydrogenolysis of carbohydrates may be safely used in food, subject to the provisions of this section:

(a) It shall contain not in excess of 0.2 percent by weight of a mixture of butanetriols.

(b) It is used or intended for use in an amount not to exceed that reasonably required to produce its intended effect.

**§ 172.867 Olestra.**

Olestra, as identified in this section, may be safely used in accordance with the following conditions:

(a) Olestra is a mixture of octa-, hepta-, and hexa-esters of sucrose with fatty acids derived from edible fats and oils or fatty acid sources that are generally recognized as safe or approved for use as food ingredients. The chain lengths of the fatty acids are no less than 12 carbon atoms.

(b) Olestra meets the following specifications:

(1) The total content of octa-, hepta-, and hexa-esters is not less than 97 percent as determined by a method entitled "Determination of Olestra by Size Exclusion Chromatography," dated December 19, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(2) The content of octa-ester is not less than 70 percent as determined by a method entitled "Measurement of the

Relative Ester Distribution of Olestra Test Material" dated December 19, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(3) The content of hexa-ester is not more than 1 percent as determined by the method listed in paragraph (b)(2) of this section.

(4) The content of penta-ester is not more than 0.5 percent as determined by the method listed in paragraph (b)(2) of this section.

(5) The unsaturated fatty acid content is not less than 25 percent (thus not more than 75 percent saturated fatty acid) and not more than 83 percent as determined by a method entitled "Measurement of the Fatty Acid Composition of Olestra Test Material," dated December 19, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(6) The content of C12 and C14 fatty acids is each not more than 1 percent, and total C20 and longer fatty acids is not more than 20 percent. C16 and C18 fatty acids make up the remainder with total content not less than 78 percent as determined by the method listed in paragraph (b)(5) of this section.

(7) The free fatty acid content is not more than 0.5 percent as determined by a method entitled "Free Fatty Acids" published in the *Official Methods and Recommended Practices of the American Oil Chemists' Society*, 3d Ed. (1985) vol. 1,